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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/635,091

08/06/2003

Anne M. Pianca

AB-185U

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05/23/2006

ADVANCED BIONICS CORPORATION  
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EXAMINER

KAHELIN, MICHAEL WILLIAM

ART UNIT

PAPER NUMBER

3762

DATE MAILED: 05/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/635,091

Applicant(s)

PIANCA ET AL.

Examiner

Michael Kahelin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4 and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Examiner could find no support in the specification for the limitation of "wherein the tube and inner core form a non-separable, solid stylet". Additionally, in paragraphs 0043, 0046, and 0047, it is disclosed that the inner core is inserted into the tube. Any negative limitation or exclusionary proviso must have basis in the original disclosure. The mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement (See MPEP 2173.05(ii)).

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 2, 5-11, 14, 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Williams et al. (US 6,214,016 hereinafter "Williams").

4. In regards to claim 1, Williams discloses a stylet (42 and 46), comprising an outer metallic covering (element 44 and col. 5, line 37), an inner core (46), and the outer and inner portions have different elastic and buckling properties (col. 5, line 37 and col. 6, line 8).

5. In regards to claims 2, 14 and 18, the outer covering is a super-elastic metallic material, which is more flexible than the inner core, (col. 5, line 39) and the inner core is a linear elastic material (col. 6, line 8), which is more resistant to buckling, and the system comprises a lead (col. 1, line 17). Please note that, since the stylet is inserted into a hollow lead (col. 6, line 63), and there are no permanent fixation means, Williams' stylet can inherently be used more than once.

6. In regards to claim 5, the stylet is isodiametric (Fig. 5).

7. In regards to claim 6, the outer covering has variable wall thickness along the length of the stylet (Fig. 6 – thickness 1 is in the region of 44 and thickness 2 is in the region of 46).

8. In regards to claim 7, the outer covering has a constant wall thickness along the length of the stylet (Figs. 5, 9 and 10).

9. In regards to claim 8, the stylet has variable outer circumference (Fig. 6 - circumference 1 is in the region of 44 and circumference 2 is in the region of 46).

10. In regards to claim 9, the outer covering (44) has constant wall thickness along the length of the stylet (Figs. 6, 9, and 10).
11. In regards to claim 10, the inner core has constant thickness along the length of the stylet (Fig. 11).
12. In regards to claim 11, the inner core material is a super-elastic material (col. 6, line 40), and the outer covering material is a linear elastic material (col. 6, line 3).
13. In regards to claim 17, the outer covering defines a tube having an annulus (Fig. 10) and the tube and inner core form a non-separable solid stylet (when the tube is advanced as in Figure 5).

***Claim Rejections - 35 USC § 103***

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claim 13 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Williams. Williams discloses the essential features of the claimed invention, including using a Nitinol inner core that has 8% recoverable strain and a radius of curvature of 0.10 inches (col. 6, line 46). Although Williams does not explicitly disclose that the core is pre-stressed, the core would inherently be required to be pre-stressed to achieve any sort of curvature during deployment. Alternatively, it is well known in the art to pre-stress Nitinol elements to impart a shape change for steering or fixation. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to pre-stress the inner Nitinol core of Williams' invention to provide a means to steer or fix the structure.

17. Claims 3, 4, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams. Williams discloses the essential features of the claimed invention, including providing an outer covering that defines a tube and annulus (Fig. 10), a non-separable solid stylet, and an outer material of Nitinol (col. 5, line 37), but does not explicitly disclose that the stainless steel of the inner core is 304, 316, or 316L stainless steel. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the stainless steel core as taught by Williams with the 304, 316, or 316L alloys because applicant has not disclosed that these alloys provide an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform

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equally well with the stainless steel as taught by Williams because both materials would provide the desired buckling resistance. Therefore, it would have been an obvious matter of design choice to modify Williams' invention by using 304, 316, or 316L stainless steel to obtain the invention as specified in the claims.

18. Claims 15, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams in view of Stoy et al. (US 5,217,026 hereinafter "Stoy"). Williams discloses the essential features of the claimed invention except for providing an outer covering of 304, 316, or 316L stainless steel and an inner core of the claimed materials. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the stainless steel outer covering (col. 6, line 3) as taught by Williams with the 304, 316, or 316L alloys because applicant has not disclosed that these alloys provide an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the stainless steel as taught by Williams because both materials would provide the desired buckling resistance. Therefore, it would have been an obvious matter of design choice to modify Williams' invention by using 304, 316, or 316L stainless steel to obtain the invention as specified in the claims. Furthermore, Stoy teaches of providing a stylet (col. 1, line 27) with a ceramic core (col. 4, line 67) to provide the rigidity required for insertion into the human body. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Williams' invention with a ceramic core to provide the rigidity required for insertion into the human body.

### ***Response to Arguments***

19. Applicant's arguments filed 4/10/2006 have been fully considered but they are not persuasive. Applicant argued that the configuration disclosed by Williams is not a stylet, but a cannula/stylet combination. However, since the stylet configuration of Williams is inserted into the lead (Figs. 4-6 and 13), the structure disclosed by Williams anticipates both the general definition of stylet (namely a stiffening member inserted into a lumen) and the special definition provided in the specification (namely "an implement inserted into the lumen of a stimulating lead to stiffen the lead and to facilitate its insertion into target tissue"; par. 0003). So although the outer tube member may or may not be a cannula, it is also a stylet.

### ***Conclusion***

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any



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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

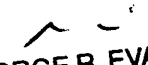
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MWK

  
5/17/06

  
GEORGE R. EVANISKO  
PRIMARY EXAMINER  
5/18/06